

January 27, 2025

Jeff Wu Acting Administrator The Center for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

Dear Acting Administrator Wu,

On behalf of the nation's Medicaid Directors, the National Association of Medicaid Directors (NAMD) is writing in response to the Center for Medicare and Medicaid Services' (CMS) proposed rule, Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.

In this rule, CMS proposes to reinterpret the statutory exclusion of weight loss drugs to require Medicaid and to allow Medicare Part D to cover these drugs when they are used for the treatment of obesity. **Medicaid agencies report significant concerns over the fiscal impacts of this proposal and strongly recommend that CMS maintain the current state option to cover or not cover anti-obesity medications.** CMS also proposes changes to improve care coordination for individuals who are dually eligible for Medicare and Medicaid. Medicaid agencies generally support these changes.

NAMD is a professional community of state and territory leaders who provide health insurance to almost 80 million individuals and families through Medicaid and the Children's Health Insurance Program in each of the 50 states, the District of Columbia and the U.S. territories. NAMD elevates thought leadership on core and emerging policy matters, amplifies the experience and expertise of Medicaid and CHIP directors, supports state programs in continuous improvement and innovation, and optimizes federal-state partnerships to help millions live their healthiest lives.

Medicaid Coverage of Anti-Obesity Medications (AOMs)

Under the Medicaid Drug Rebate Program, Medicaid agencies must cover almost all Food and Drug Administration (FDA)-approved outpatient drugs from participating manufacturers. However, section 1927(d)(2) of the Social Security Act outlines a small group of drugs – including drugs "used for anorexia, weight loss, or weight gain" – that can be excluded from coverage. This statutory exclusion means that, under current regulation, states have the option but are not required to cover weight loss and obesity drugs through their Medicaid programs.

Over the past several years, the FDA has approved new GLP-1 (glucagon-like peptide-1) drugs for the treatment of obesity (Wegovy, Saxenda, and Zepbound), for the treatment of Type 2 diabetes (Ozempic, Rybelsus, Victoza, and Mounjaro), and to prevent heart attacks or strokes in adults with cardiovascular disease (Wegovy). Under the Medicaid Drug Rebate Program, states must cover these drugs when used to treat Type 2 diabetes or to prevent heart attacks or strokes in adults with cardiovascular disease but have the option to cover them for the treatment of obesity. As of August 2024, thirteen state Medicaid agencies have elected to cover GLP-1s for the treatment of obesity. Despite this limited coverage footprint, Medicaid spending on these drugs has increased rapidly, with gross spending increasing by over 500% from 2019 to 2023.

In this rule, CMS proposes to reinterpret the statutory exclusion of weight loss drugs to require Medicaid and to allow Medicare Part D to cover these drugs when they are utilized for weight loss or chronic weight management for the treatment of obesity. Medicaid agencies report significant concern about the fiscal impacts of this proposal and strongly recommend that CMS maintain the state option to cover or not cover anti-obesity medications.

Fiscal Impacts

Medicaid agencies report that CMS's proposal to require coverage of AOMs for the treatment of obesity would have significant fiscal impacts. Medicaid agencies who do not currently cover AOMs for the treatment of obesity project that the requirement would result in \$30 million to \$79 million in total gross spending per year in small states and \$50 million to \$126 million per year in medium-sized states. These projections align with experiences of states who have elected to cover GLP-1s for weight loss indications. One medium-sized state, for example, reported approximately \$15 million in spending on GLP-1s for weight loss in the past fiscal quarter; another medium-sized state reported \$172 million in spending on GLP-1s for weight loss in fiscal year 2024. These cost estimates do not account for additional AOMs coming to market or existing medications receiving new indications for the treatment of obesity, which would further increase costs.

Pharmaceutical companies have argued that coverage of AOMs may lead to significant savings to the health care system, due to the costs associated with obesity and related chronic illnesses. However, according to an <u>analysis by the Congressional Budget</u>

Office (CBO), there are no empirical studies that "directly link the use of AOMs or other weight-loss treatments to reductions in other health care spending." <u>Economic models</u> have also projected that the cost of AOMs would significantly outweigh cost savings due to reduced utilization of other health care services.

Medicaid agencies report that the high cost of these drugs represents a significant threat to the sustainability of their programs. Unlike the federal government, states operate under balanced budget requirements, meaning that large increases in spending on pharmacy would necessitate cost-saving measures elsewhere

in the program. If CMS finalizes a requirement to cover AOMs, Medicaid agencies would likely have to make reductions to other benefits or eligibility categories, threatening the ability of Medicaid programs to provide sustainable, high-value care for all their members.

Operational Impacts

In addition to the fiscal impacts discussed above, Medicaid agencies report that the proposed requirement to cover AOMs for the treatment of obesity would have operational impacts on their programs. In some cases, states would need to update state-level regulations that exclude coverage of medications used for weight loss. Additionally, Medicaid agencies would need to develop or refine utilization management criteria and preferred drug lists, and may need to hire additional call center and prior authorization review staff, given the anticipated level of interest in AOMs. Finally, Medicaid agencies that use managed care to cover their pharmacy benefits would need to amend capitation rates and may need to renegotiate managed care contracts to account for the cost of AOMs. Due to these operational impacts, Medicaid agencies would need at least two years to implement the proposed coverage change if it were finalized.

Coverage Criteria and Utilization Management

CMS proposes to require that Medicaid agencies cover anti-obesity medications (AOMs) when used for the treatment of obesity. Specifically, Medicaid agencies would be required to cover AOMs when used for chronic weight management and weight maintenance for individuals with obesity, but not when used for chronic weight management in individuals who are overweight but do not have obesity. As discussed above, Medicaid agencies are required to cover AOMs when used for an FDA-approved indication other than chronic weight management (e.g., Type 2 diabetes indication for Ozempic, Rybelsus, Victoza, and Mounjaro; cardiovascular indication for Wegovy). Under the proposed rule, Medicaid agencies would not be required to cover AOMs for chronic weight management in individuals with overweight in the presence of other weight-related comorbidities, such as hypertension or dyslipidemia, that do not have a separate FDA indication.

Medicaid agencies report concern over these coverage criteria. As noted in the proposed rule, these coverage criteria may create an incentive for individuals to gain weight to become eligible for coverage of AOMs. Additionally, these coverage criteria may lead to confusion and abrasion with providers and members, as it can be difficult to explain why AOMs are not covered for individuals who are overweight and have weight-related comorbidities. NAMD strongly recommends that CMS maintain the option for states to cover or not cover AOMs. If CMS does finalize the requirement that Medicaid agencies cover AOMs for the treatment of obesity, Medicaid agencies should retain the authority to develop coverage criteria, including around length of coverage.

Effective Date

CMS proposes an effective date for this requirement of 60 days after publication of the final rule. Given the fiscal and operational impacts discussed above, Medicaid agencies report that this effective date would be untenable. State budget processes typically begin a full year before enactment of the budget, meaning that states would not be able to incorporate the fiscal impact of coverage of AOMs into their existing budgets. These challenges would be exacerbated in the twenty states that have biennial budget processes. Additionally, states would need to develop prior authorization criteria and preferred drug lists, amend managed care capitation rates, and ensure they have capacity to manage call centers and prior authorization review processes. If CMS finalizes the requirement to cover AOMs for the treatment of obesity, NAMD strongly recommends an extended implementation deadline of at least two years.

In Medicare, there is a requirement that CMS not implement regulations that significantly impact Medicare prescription drug plan sponsors other than at the beginning of the calendar year. This would create a time period during which Medicaid agencies would be required to cover AOMs but Part D plans could not cover AOMs.

Medicaid agencies report that this misalignment of coverage timelines would lead to fiscal and operational challenges.

During this time period, Medicaid agencies would be responsible for the full cost of these medications for dually eligible members, increasing the fiscal impact on states. Additionally, this misalignment in effective dates would likely lead to confusion for dually eligible members, who would experience a change in payers after Part D coverage begins. These members may experience a change in medications or a disruption in treatment if their Medicaid and Part D plans have different formularies and/or different authorization criteria; this may lead to low-efficacy treatment or rapid cycling of weight loss followed by weight gain. States report that this misalignment would also lead to challenges around drug utilization review, as Medicaid agencies do not receive Part D claim information for dually eligible members. Finally, states report concerns around potential therapeutic duplication if, for example, an individual is receiving a GLP-1 for Type 2 diabetes through Medicare and another GLP-1 for the treatment of obesity through Medicaid; CMS should confirm that Medicaid agencies can exclude coverage of AOMs if the member is already receiving a duplicate AOM through Medicare. If CMS finalizes this provision, NAMD strongly recommends aligning coverage timelines across Medicaid and Medicare Part D to address these challenges.

Policies to Support Coordination of Care for Dually Eligible Individuals

In this rule, CMS proposes to require Dual Eligible Special Needs Plans (D-SNPs) that are applicable integrated plans (AIPs) to (1) have integrated member identification (ID) cards that serve as the ID cards for both the Medicare and Medicaid plans in which a

member is enrolled; and (2) conduct an integrated health risk assessment (HRA) for Medicare and Medicaid, rather than separate HRAs for each program. CMS also proposes to require all SNPs (i.e., D-SNPs, chronic condition SNPs, and institutional SNPs) to meet certain timeframes for conducting Health Risk Assessments and developing individualized care plans (ICPs) and prioritize the involvement of the enrollee or their representative in the development of the individualized care plan. **Medicaid agencies are generally supportive of these changes.**

Integrating Member ID Cards for Dually Eligible Enrollees in Certain Integrated D-SNPs CMS proposes to require D-SNPs that are applicable integrated plans (AIPs) to have integrated member identification (ID) cards. **Medicaid agencies generally support this proposal.** CMS seeks feedback on if they should consider applying this requirement to all Highly Integrated Dual Eligible (HIDE) SNPs. Medicaid agencies report that it would be very difficult for plans to create integrated materials when enrollment is not exclusively aligned, and that CMS should only apply this requirement to AIPs.

Integrating Health Risk Assessments for Dually Eligible Enrollees in Certain Integrated D-SNPs

In this rule, CMS proposes to require all D-SNPs that are AIPs to conduct a comprehensive health risk assessment (HRA) that meets all applicable Medicare and Medicaid requirements, such that enrollees in the AIP complete a single, integrated HRA. **Medicaid agencies support the intention of this proposal but report operational concerns.** Some Medicaid agencies use their existing Medicaid HRAs for non-dually eligible members and must maintain consistency across populations for programmatic, systems, and analytic reasons. For example, one state uses their HRAs to stratify members (including non-dually eligible members) to different levels of care coordination. If CMS finalizes this proposal, they should provide one-on-one technical assistance to states to reduce disruption to existing processes and systems, along with an extended implementation deadline.

Promoting Person-centeredness in SNP ICPs and Timeliness of HRAs and Individualized Care Plans

CMS proposes several changes to improve timeliness and person-centeredness of HRA and individualized care plan (ICP) processes for SNPs (i.e., D-SNPs, chronic condition SNPs, and institutional SNPs). **Medicaid agencies are generally supportive of these changes but report some operational feedback**.

Regarding the proposed timeliness standards for HRAs, Medicaid agencies seek clarification on how the proposed standards would interact with the timeliness standards that Medicaid agencies currently specify in their contracts with plans.

Regarding the proposed requirements around ICPs, Medicaid agencies note that requiring real-time involvement of the member in the drafting of the ICP can lead to delays in care; instead, CMS should allow the care team to draft the ICP based on the member's health care goals and preferences, review the ICP with the member, and then adjust the ICP based on feedback from the member. CMS seeks comment on if they should allow additional time for the development of the ICP, beyond 30 days. Medicaid agencies report that additional time (up to 90 days) can be helpful when developing ICPs in rural areas with limited service availability. Additional time would also allow D-SNPs to prioritize ICP development based off a member's risk level. Finally, CMS seeks comment on if they should not require ICPs in circumstances where the member cannot be reached or declines to participate. While some Medicaid agencies support this flexibility, other agencies report that ICPs should be developed for all enrolled members, regardless of their participation in the process.

Comment Solicitation – Making State Medicaid Agency Contracts Public

CMS seeks comment on if they should post State Medicaid Agency Contracts (SMACs) with D-SNPs online. Medicaid agencies do not report concerns with this proposal, as long as they can continue redacting any confidential or financial information from their SMACs. Many Medicaid agencies already post their SMACs online, and report that their SMACs generally do not contain confidential or financial information.

Thank you for the opportunity to provide comments on this proposed rule. NAMD looks forward to continuing to work with CMS to improve care for Medicaid members.

Sincerely,

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